We claim:

1. An assaying device for detecting the presence of pathogenic prion protein in a biological sample and in material made from a biological sample, comprising:

a digestive pad having proteinase-K immobilized therein for removing nonpathogenic prion protein from the biological sample;

a conjugate pad having a labeled first antibody of an antibody pair to pathogenic prion protein; the conjugate pad being in fluid communication with the digestive pad; and,

a test strip having an immobilized second antibody of the antibody pair for producing a response indicative of the presence or concentration of the pathogenic prion protein; the test strip being in fluid communication with the conjugate pad.

2. The device of claim 1 wherein the test strip has pores of a diameter sufficient to allow the labeled first antibody to migrate laterally through the test strip toward the immobilized antibody.

3. The device of claim 1 wherein the proteinase-K is bound covalently to the digestive pad.

4. The device of claim 1 wherein the proteinase-K is conjugated to components impregnated in the digestive pad.

5. The device of claim 1 wherein the proteinase-K is immobilized on a solid support selected from latex beads, rod-shaped bodies coated with latex, micro- or nanoparticles, and a porous membrane pad.

6. The device of claim 1 wherein the proteinase-K is in a gelled substance contained in the digestive pad.

7. The device of claim 1 wherein the amount of immobilized proteinase K in the digestive pad is sufficient to substantially digest all protein in the sample.

8. The device of claim 4 wherein the support comprises latex beads having an average diameter of from about 1 to about 10 microns.

9. The device of claim 1 wherein the amount of immobilized enzyme in the digestive pad ranges from about 30 μg to about 400 μg.

10. The device of claim 1 wherein the amount of immobilized enzyme in the digestive pad ranges from about 100 μg to about 350 μg.

11. The device of claim 1 wherein the labeled first antibody has a label selected from latex beads, rod-shaped bodies coated with latex, particles comprising a dye, colloidal particles, metal particles, micro- and nanoparticles, fluorescent compounds, chemiluminescent compounds, and magnetic beads.

12. The device of claim 1 wherein the labeled antibody has a colored label.

13. The device of claim 1 wherein the antibodies are each specific for a particular epitope of the pathogenic prion protein.

14. The device of claim 1 wherein the digestive pad and the conjugate pad lie adjacent each other in substantially the same plane.

15. The device of claim 1 further comprising a spacer pad between the digestive pad and the conjugate pad to allow for longer digestion of the nonpathogenic prion protein.

16. The device of claim 1 wherein the digestive pad and the conjugate pad comprise separate portions of a single pad.

17. The device of claim 1 wherein the digestive pad comprises at least one material selected from the group consisting of gauze, cellulose, cellulose acetate, polyesters, and porous materials.

18. The device of claim 1 wherein the conjugate pad comprises at least one of plastic filter bed in glass filter, polyester, plastic bonded glass fiber, and nonwoven polymeric materials.

19. The device of claim 1 wherein the test strip comprises at least one material selected from nitrocellulose, cellulose, glass fiber, bonded glass fiber, polyesters, nylon, and polyethylsulphone.

20. The device of claim 1 wherein each of the digestive pad, the conjugate pad, and the test strip are distinct portions of one composite test pad.

21. The device of claim 1 further comprising a control line for confirming the device is working, the control line comprising an antibody to the labeled first antibody.

22. An assaying device for detecting the presence of pathogenic prion protein in a biological sample and in material made therefrom comprising:

proteinase-K immobilized on a support;

a conjugate pad impregnated with a labeled first antibody to the pathogenic prion protein for complexing with the pathogenic prion protein; and,

a test strip having a first end, a second end, and an immobilized second antibody to the pathogenic prion protein immobilized between the conjugate pad and the second end, such that

the immobilized antibody produces a detectable change in the presence of the pathogenic prion protein;

the conjugate pad is disposed between and in fluid communication with the proteinase support and the test strip.

23. The device of claim 22 wherein the proteinase-K support is one of a digestive pad or components impregnated in the digestive pad.

24. The device of claim 22 wherein the proteinase-K is immobilized on a solid support selected from latex beads, rod-shaped bodies coated with latex, micro- or nanoparticles, and a porous membrane pad.

25. The device of claim 22 wherein the proteinase-K is in a gelled substance contained in a digestive pad.

26. The device of claim 22 wherein the amount of proteinase-K immobilized in the digestive pad is sufficient to substantially digest all protein in the sample.

27. The device of claim 24 wherein the support is of a size too large to move through pores in the test strip.

28. The device of claim 22 wherein the amount of immobilized proteinase-K ranges from about 30 μg to about 400 μg.

29. The device of claim 22 wherein the amount of immobilized proteinase-K ranges from about 100 μg to about 350 μg.

30. The device of claim 22 wherein the label on the first antibody is selected from latex beads, rod-shaped bodies coated with latex, particles comprising a dye, colloidal particles, metal particles, micro- and nanoparticles, fluorescent compounds, chemiluminescent compounds, and magnetic beads.

31. The device of claim 22 wherein the labeled antibody has a colored label.

32. A test system for detecting pathogenic prion protein in animals or humans comprising:

(a) proteinase-K immobilized on a support;

(b) a porous membrane for a sample substantially free of the nonpathogenic prion protein to migrate laterally therethrough by capillary action; and,

(c) a pair of antibodies specific to the pathogenic prion, one antibody being a labeled antibody for complexing with pathogenic prion protein, and the other antibody being immobilized on the membrane for capturing the labeled antibody complex and producing a corresponding response in the test strip.

33. The system of claim 32 wherein the support is separate from the test strip.

34. The system of claim 32 wherein the support for the proteinase-K is selected from the group consisting of magnetic beads, latex supports, filter tips, microcrystalline particles, colloidal particles, conjugate supports, plastic surfaces, and glass surfaces.

35. The system of claim 32 wherein the proteinase-K is covalently bound to the support.

36. The system of claim 32 wherein the proteinase K is present on the support in an amount sufficient to substantially digest all protein in the sample.

37. The system of claim 32 wherein the proteinase-K is present on the support in an amount ranging from about 30 μg to about 400 μg.

38. The system of claim 32 wherein the proteinase-K is present on the support in an amount ranging from about 100 μg to about 350 μg.

39. The system of claim 32 wherein the membrane has pores of a diameter sufficient to allow the labeled antibody complex to migrate laterally therethrough toward the immobilized antibody.

40. The system of claim 32 wherein the labeled antibody is in a conjugate pad in fluid communication with the membrane.

41. The system of claim 32 wherein the labeled antibody has a colored label.

42. The system of claim 32 wherein the labeled antibody has a label selected from latex beads, rod-shaped bodies coated with latex, particles comprising a dye, colloidal particles, metal particles, micro- and nanoparticles, fluorescent compounds, chemiluminescent compounds, and magnetic beads.

43. The system of claim 42 wherein the label is a latex bead having an average diameter of from about 50 to about 500 nanometers.

44. The system of claim 32 wherein the membrane comprises at least one material selected from nitrocellulose, cellulose, glass fiber, bonded glass fiber, polyesters, nylon, and polyethylsulphone.

45. The system of claim 32 further comprising a control line for confirming the system is operating properly, the control line comprising an antibody to the labeled antibody.

46. A test kit for rapid detection of pathogenic prion in a sample containing a biological material obtained from an animal or a human, comprising:

(a) a buffer for homogenizing a sample containing biological material obtained from an animal or a human;

(b) proteinase-K immobilized on a support for removing nonpathogenic prion protein from the homogenized sample;

(c) a porous membrane for the sample substantially free of the nonpathogenic prion protein to migrate laterally by capillary action; and

(d) a pair of antibodies specific to the pathogenic prion, one antibody being a labeled antibody for complexing with the pathogenic prion protein present in the sample, and the other antibody being immobilized on the membrane for capturing the labeled antibody complex and producing a corresponding response.

47. The test kit of claim 46 wherein the buffer comprises at least one emulsifier or surfactant, casein, at least one polysaccharide, salt, albumin, and a sufficient quantity of water to form a mixture.

48. The test kit of claim 47 wherein the at least one emulsifier or surfactant in the buffer is selected from octoxynol, nonoxynol, polyglycol ether, polyoxythylene (10) isooctylphenyl ether, sodium dodecyl sulfate, and sodium deoxycholate.

49. The test kit of claim 47 wherein the at least one polysaccharide in the buffer is selected from sucrose, mannose, trehalose, and maltose.

50. The test kit of claim 47 wherein the buffer comprises a denaturing agent.

51. The test kit of claim 46 wherein the buffer has an ionic strength of from about 200 to about 400 mM.

52. The test kit of claim 46 wherein the support for the proteinase-K is external to the membrane.

53. The test kit of claim 52 wherein the support for the proteinase-K is selected from the group consisting of magnetic beads, latex supports, filter tips, microcrystalline particles, colloidal particles, conjugate supports, plastic surfaces, and glass surfaces.

54. The test kit of claim 46 wherein the proteinase-K immobilized on the support is present in an amount ranging from about 30 μg to about 400 μg.

55. The test kit of claim 46 wherein the proteinase-K immobilized on the support is present in an amount ranging from about 100 μg to about 350 μg.

56. The test kit of claim 46 wherein the labeled antibody has a colored label.

57. The test kit of claim 46 wherein the labeled antibody has a label selected from latex beads, rod-shaped bodies coated with latex, particles comprising a dye, colloidal particles, metal particles, micro- and nanoparticles, fluorescent compounds, chemiluminescent compounds, and magnetic beads.

58. The test kit of claim 46 wherein the label on the antibody is a latex bead having an average diameter of from about 50 to about 500 nanometers.

59. The test kit of claim 46 wherein the membrane comprises at least one material selected from nitrocellulose, cellulose, glass fiber, bonded glass fiber, polyesters, nylon, and polyethylsulphone.

60. The test kit of claim 46 further comprising a control line for confirming the device is working, the control line having an antibody to the labeled first antibody.

61. The test kit of claim 46 producing a test result within from about 0.5 to about 20 minutes after the sample is introduced to the porous membrane.

62. A test kit for rapid detection of pathogenic prion protein in a vertebrate, comprising:

(a) a buffer for extracting prion protein from a sample containing biological material obtained from a vertebrate;

(b) proteinase-K immobilized in a digestive pad for digesting the noninfectious prion protein in the sample;

(c) a test strip having an immobilized antibody of an antibody pair to the pathogenic prion protein, the test strip being in fluid communication with the digestive pad; and

(d) a labeled antibody to the pathogenic prion protein for producing a readable response indicative of the presence or concentration of the pathogenic prion protein.

63. The test kit of claim 62 wherein the test strip has pores of a diameter sufficient to allow the labeled antibody to migrate laterally through the test strip toward the immobilized antibody.

64. The test kit of claim 62 wherein the proteinase-K is covalently bound to the digestive pad.

65. The test kit of claim 62 wherein the proteinase-K is in a gelled substance contained in the digestive pad.

66. The test kit of claim 62 wherein the proteinase-K is immobilized on a support selected from latex beads, rod-shaped bodies coated with latex, micro- or nanoparticles, and a porous membrane pad.

67. The test kit of claim 62 further comprising a conjugate pad in fluid communication with the test strip, the labeled antibody being disposed in the conjugate pad.

68. The test kit of claim 62 wherein the proteinase-K is present in an amount ranging from about 30 μg to about 400 μg.

69. The test kit of claim 62 wherein the proteinase-K is present in an amount ranging from about 100 μg to about 350 μg.

70. The test kit of claim 62 wherein the labeled antibody has a colored label.

71. The test kit of claim 62 wherein the labeled antibody has a label selected from latex beads, rod-shaped bodies coated with latex, particles comprising a dye, colloidal particles, metal particles, micro- and nanoparticles, fluorescent compounds, chemiluminescent compounds, and magnetic beads.

72. The test kit of claim 67 further comprising a spacer pad between the digestive pad and the conjugate pad to allow for longer digestion of the nonpathogenic prion protein.

73. The test kit of claim 67 wherein the digestive pad and the conjugate pad comprise separate portions of a single pad.

74. The test kit of claim 62 wherein the digestive pad comprises at least one material selected from the group consisting of gauze, cellulose, cellulose acetate, polyesters, and porous materials.

75. The test kit of claim 62 wherein the conjugate pad comprises at least one of plastic filter bed in glass fiber, polyester, plastic bonded glass fiber and nonwoven polymeric materials.

76. The test kit of claim 62 wherein the test strip comprises at least one material selected from nitrocellulose, cellulose, glass fiber, bonded glass fiber, polyesters, nylon, and polyethylsulphone.

77. The test kit of claim 67 further comprising a control line for confirming the device is working, the control line comprising an antibody to the labeled first antibody.

78. A test device for detecting pathogenic prion comprising:

(a) proteinase-K immobilized on a support in an amount sufficient to substantially digest all noninfectious prion protein in a test sample;

(b) a labeled first antibody specific to the prion protein; and

(c) a membrane for lateral flow, having a first end, a second end, and second antibody to the prion protein immobilized therebetween; the first end being in fluid communication with the proteinase-K support and the labeled antibody;

such that the prion protein in an enzyme-treated sample migrates toward the second end of the membrane and binds with both of the antibodies to indicate the presence or concentration of prion protein in the test sample.